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Patent Application
Attorney Docket No. PC11078C
U.S. Serial No.: 10/801,471

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By Rebecca Pesantez
(Signature of person mailing)
Rebecca Pesantez
(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: **LYSSIKATOS ET AL.**

APPLICATION NO.: **10/801,471**

FILING DATE: **MARCH 15, 2004**

TITLE: **CRYSTAL FORMS OF 6-[(4-CHLORO-PHENYL)-HYDROXY-(3-METHYL-3H-IMIDAZOL-4-YL)-METHYL]-4-(3-ETHYNYL-PHENYL)-1-METHYL-1H-QUINOLIN-2-ONE, 2,3-DIHYDROXYBUTANEDIOATE SALTS AND METHOD OF PRODUCTION**

Examiner: **Morris, Patricia L.**

Group Art Unit: **1625**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT
UNDER 37 C.F.R. §§ 1.111 and 1.143

This paper is filed in response to a Restriction Requirement mailed on July 15, 2005 concerning the above-referenced patent application. A shortened statutory period for response to the July 15, 2005 Office Action was set to expire one month from the mailing date of the Action, i.e., August 15, 2005. Accordingly, a petition for an extension of time (one month) and requisite fee are attached herewith. No additional fee is believed due. However, if any fee is due, the Examiner is authorized to charge the fee to Applicants' Deposit Account No. 16-1445.

Claims 29 - 35 are pending in the present application. The Examiner has subjected claims 29 - 35 to restriction under 35 U.S.C. 121 to one of the following 3 groups:

Group I: Claims 29 - 32, drawn to a process of preparing;

Group II: Claims 33 and 34, drawn to multiple uses; and

Group III: Claims 25, drawn to a method of using an unknown additional active ingredient.

Applicants hereby elect with traverse for further prosecution in this application the invention identified in the Office Action as "Group III, claim 35, drawn to a method using an unknown additional

active ingredient." Applicants expressly reserve the right to file at a later date one or more divisional applications directed to the subject matter of the non-elected groups. In the July 15, 2005 Office Action, the Examiner stated that "in the event of an election of Group III, applicants are requested to elect a single disclosed mixture." Applicants hereby elect the crystal form of 6-[(4-chloro-phenyl)-hydroxy-(3-methyl-3H-imidazol-4-yl)-methyl]-4-(3-ethynyl-phenyl)-1-methyl-1H-quinolin-2-one, 2,3-dihydroxybutanedioate anhydrous salt in combination with a growth factor inhibitor in order to expedite the prosecution of the subject application.

Applicants traverse the Examiner's rejection on the grounds that it is improper and an abuse of discretion to restrict in the present situation because prosecution of the restricted subject matter in one application would not place a serious burden on the Examiner. M.P.E.P. § 803. According to M.P.E.P. § 803, the Examiner can only restrict patentably distinct inventions when (1) the inventions are independent or distinct as claimed and (2) where there is a serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that the Examiner has made no showing that prosecuting the claims of the invention in one application would be burdensome. The prosecution of all of the claims in the same application would not be burdensome because the Examiner would be required to search the same class and sub-class in order to determine patentability of any of Groups II and III. Furthermore, Applicants respectfully traverse the Examiner's restriction of the process of preparing from the uses of the compounds. The Examiner has all the relevant art in front of her. There is no burden of prosecuting the uses of the compounds with the processes of preparing the compounds. Applicants therefore submit that the Examiner's requirement of restriction is improper. Where there is no serious burden examination of the entire case "must" occur. Here the MPEP is clear:

> If the search and examination of the entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. (MPEP § 803) (emphasis added).

In view of the above, Applicants submit that the restriction requirement is improper and respectfully requests that the Examiner withdraw the restriction requirement so as to allow claims 29 - 32 to be prosecuted in the same application.

In the interest of resolving the restriction dispute, however, Applicants herein propose an alternate restriction that if acceptable to the Examiner and the Examiner would adopt they would not oppose. Simply, Applicants propose that the total invention be apportioned within a reasonable number of groups. Applicants' Proposed Groupings are as follows:

Group I: Claims 29 – 32, drawn to a process of preparing.

Group II: Claims 33 - 35, drawn to methods of treating hyperproliferative disorders.

If the Examiner adopts Applicants' proposed grouping then Applicants herein elect without traverse Group II and maintain, for purposes of election, the same combination identified above, i.e a crystal form of 6-[(4-chloro-phenyl)-hydroxy-(3-methyl-3H-imidazol-4-yl)-methyl]-4-(3- ethynyl-phenyl)-1-methyl-1H-quinolin-2-one, 2,3-dihydroxybutanedioate anhydrous salt in combination with a growth factor inhibitor, and further elect lung cancer in response to Examiner's request that "in the event of an election of Group II, applicants are requested to elect a single disclosed method." Applicants respectfully submit that the above offer is made in an effort to expedite prosecution. Applicants firmly maintain that restriction is not proper in the present situation for the reasons described below because there is no serious burden on the Examiner to search all of the claimed subject matter in the present application. Applicants submit that they have endeavored to provide a complete restriction of the claims that they believe should be acceptable to the Examiner. This is so because the proposed restriction is directed to embodiments of methods of treating hyperproliferative diseases. Furthermore, Examiner has already combined claims 33 - 34 around class 514. Likewise, Group III, claim 35, combines the same classification. Applicants thus submit that the Examiner will be able to expeditiously search each of the grouped methods in an efficient manner that will not impose an undue burden on the Patent and Trademark Office nor unduly deprive the Applicant of his right to claim the invention as he sees fit.

In conclusion, Applicants submit that all pending claims are patentable, and respectfully request that they be allowed to issue. In the event that there are any questions relating to this Response or to the application in general, the Examiner is requested to telephone the undersigned concerning such questions so that the prosecution of this application can be expedited.

Respectfully submitted,

Date 9/14/05

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